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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,721	02/09/2004	Ralf Jockers	FRAV2003/0005USNP	9535

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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,721	JOCKERS ET AL.	
	Examiner	Art Unit	
	Louis V. Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1–11 and 14–17 drawn to oligonucleotides that hybridize to SEQ ID No. 1, and to expression vectors and host cells thereof, classified in class 536, subclass 24.5.

II. Claims 12–17 and 42–44, drawn to oligonucleotides that hybridize to SEQ ID No. 21, and to vectors and host cells thereof, classified in class 536, subclass 24.5. Election of this group requires the further election of a single oligonucleotide sequence from Claim 42 or 43, as explained below.

III. Claim 18, drawn to the use of an oligonucleotide to produce a medicinal product for treating leptin-related conditions, classified in class 514, subclass 44.

IV. Claim 18, drawn to the use of a vector to produce a medicinal product for treating leptin-related conditions, classified in class 514, subclass 44.

V. Claim 18, drawn to the use of a host cell comprising a vector to produce a medicinal product for treating leptin-related conditions, classified in class 435, subclass 325.

VI. Claims 19–23, drawn to fusion proteins consisting of: 1) a sequence exhibiting at least 65% identity with SEQ ID. No. 4; and 2) an energy-donor or acceptor protein, classified in class 530, subclass 350. Election

of this group requires the further election of a single protein sequence, recited in Claim 23, as explained below.

VII. Claims 19–23, drawn to fusion proteins consisting of: 1) a sequence exhibiting at least 65% identity with SEQ ID. No. 16; and 2) an energy-donor or acceptor protein, classified in class 530, subclass 350. Election of this group requires the further election of a single protein sequence, recited in Claim 23, as explained below.

VIII. Claims 24–32, drawn to nucleic acids that encode the proteins of Inventions VI and VII, and to host cells and fragments of host cells thereof, classified in class 530, subclass 350. Election of this group requires the further election of a single nucleic acid sequence, recited in Claim 25, as explained below.

IX. Claims 33–41, drawn to methods of testing compounds for their ability to alter the interaction between a protein and the leptin receptor, wherein the protein exhibits at least 65% identity with SEQ ID. No. 4, classified in class 435, subclass 7.1, for example. Election of this group requires the further election of a single protein sequence, recited in Claim 40, as explained below.

X. Claims 33–41, drawn to methods of testing compounds for their ability to alter the interaction between a protein and the leptin receptor, wherein the protein exhibits at least 65% identity with SEQ ID. No. 16, classified in class 435, subclass 7.1, for example. Election of this group requires the

further election of a single protein sequence, recited in Claim 40, as explained below.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions I and II appear to be directed to patentably distinct oligonucleotides, vectors and host cells, having different structures, functions, and compositions, wherein each is capable of separate manufacture and use. For example, the products of Group I comprise oligonucleotides that specifically hybridize with SEQ ID No. 1, whereas the products of Group II comprise oligonucleotides that specifically hybridize with SEQ ID No. 21. On their face, SEQ ID Nos. 1 and 21 appear to be structurally distinct sequences, requiring separate searches of the prior art. If it is shown that SEQ ID No. 21 comprises SEQ ID No. 1, in its entirety, the requirement for restriction will be withdrawn and the inventions rejoined.

Inventions III–V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are directed to methods that are distinct both physically and functionally, having different modes of operation and function. For example, Invention III requires the use of an oligonucleotide, which is not required by Inventions

IV or V. Invention III requires the use of a vector, which is not required by Inventions III or V. Invention V requires the use of a host cell, which is not required by Inventions III or IV.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they are drawn to patentably distinct products, wherein each has a different structure and function, which require separate searches, and wherein each is capable of separate manufacture and use. For example, Invention VI is drawn to fusion proteins having a sequence that is at least 65% identical to SEQ ID. No. 4, which is not a requirement for Invention VII, which is drawn to fusion proteins having a sequence that is at least 65% identical to SEQ ID. No. 16. On their face, SEQ ID. Nos. 4 and 16 appear to be structurally and functionally distinct, requiring separate searches of the prior art. Thus, restriction for the purposes indicated is proper.

Inventions I and II and III–V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product oligos can be used as probes in Northern blotting analyses to monitor the expression of specific mRNA transcripts in cells and tissues, which does not involve using the oligos

in medicinal products to prevent or treat leptin-related conditions as in Inventions III–V. The product vector can be used as a transfection, transformation, or infection marker, which does not involve using the vector in medicinal products to treat or prevent leptin-related conditions. The product host cells can be used in methods of screening to identify gene isoforms refractory to knockdown by the claimed oligonucleotides or to identify gene products that complement the activity of OB-RGRP.

Inventions I and II are unrelated to Inventions VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are drawn to physically and functionally distinct products that are capable of separate manufacture and use. For example, Inventions I and II are directed to antisense oligonucleotides, vectors, and host cells, whereas Inventions VI and VII are directed to fusion proteins.

Inventions I and II are unrelated to Invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are drawn to physically and functionally distinct products that are capable of separate manufacture and use. For example, Inventions I and II are directed to antisense oligonucleotides, vectors, and host cells that are unrelated to Invention VIII, which is directed to nucleic acids that encode fusion proteins.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are directed to methods that are distinct both physically and functionally, and are not required one for the other. For example, Invention IX requires the use of a protein that is at least 65% identical to SEQ ID. No. 4, which is not required by Invention X, which requires the use of a protein that is at least 65% identical to SEQ ID. No. 16.

Inventions I and II are unrelated to Inventions IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions I and II are drawn to antisense oligonucleotides, vectors, and host cells that are not disclosed as useful with the methods of Invention IX and X. Groups IX and X are directed to methods for determining the modification of the interaction between a protein and the leptin receptor and comprise the use of compounds and proteins that are unrelated to the antisense oligos, vectors, and host cells of Inventions I and II.

Inventions III–V are unrelated to Inventions VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions VI and VII are drawn to fusion protein products that are not disclosed as useful with the methods of Inventions III–V, which

require the use of oligonucleotides, vectors, and host cells to produce a medicinal product.

Inventions III–V are unrelated to Invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention VIII is directed to nucleic acids that encode fusion proteins, which are not disclosed as useful in the methods of Inventions III–V. Inventions III–V require the use of antisense oligonucleotides, vectors, and host cells to produce a medicinal product, which is unrelated to the nucleic acids of Invention VIII.

Inventions III–V are unrelated to Inventions IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are drawn to physically distinct methods that have different modes of operation, function, and effect. For example, Inventions III–V require the use of antisense oligonucleotides, vectors, and host cells to produce a medicinal product, which is not a step required in the methods for measuring the interaction between a protein and the leptin receptor, according to Inventions IX and X.

Inventions VI and VII are unrelated to Invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are unrelated because

they are directed to physically and functionally distinct molecules, which are capable of separate manufacture and use. For example, Inventions VI and VII are directed to fusion proteins, which are structurally and chemically distinct from the nucleic acids of Invention VIII.

Inventions VI and VII are related to Inventions IX and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product fusion proteins of Inventions VI and VII can be used as controls in protein detection and quantitation assays, which does not involve administering the proteins to cells or fragments of cells as in Inventions IX and X.

Because these inventions are distinct one from the other for the reasons given above, and because the searches for each are divergent and not co-extensive, examining all these inventions in a single application presents a serious burden on the examiner. Thus, restriction for the purposes indicated is proper.

Further Election

Should Applicants elect to prosecute Group II, this Group is subject to further restriction as follows.

Claims 42 and 43 claim oligonucleotides having at least 60% identity with SEQ ID Nos. 37, 38, and 42. Although the sequences corresponding to SEQ ID Nos. 37, 38, and 42 each target and modulate expression of the same gene, the instant oligonucleotide sequences are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct: each oligonucleotide sequence has a unique nucleotide sequence, and each oligonucleotide sequence targets a different and specific region of the sequence corresponding to SEQ ID No. 21. Furthermore, a search of more than one (1) of the oligonucleotide sequences claimed in claims 42 and 43 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) oligonucleotide sequence from either claim 42 or 43 for prosecution with Group II. If, as it appears, SEQ ID Nos. 37 and 38 are in fact complements of one another, the restriction as to SEQ ID Nos. 37 and 38 will be withdrawn and the inventions rejoined.

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Should Applicants elect to prosecute Group VI or VII, each of these Groups is subject to further restriction as follows.

Claim 23 claims fusion protein SEQ ID Nos. 6, 8, 18, and 20. The instant fusion protein sequences are considered to be unrelated, since each sequence claimed is structurally and functionally distinct. Furthermore, a search of more than one (1) of the

fusion protein sequences claimed in claim 23 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) fusion protein sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) fusion protein sequence from claim 23 for prosecution with Group VI or VII.

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Should Applicants elect to prosecute Group VIII, this Group is subject to further restriction as follows.

Claim 25 claims nucleic acid SEQ ID Nos. 5, 7, 17, and 19. The instant nucleic acid sequences are considered to be unrelated, since each sequence claimed is structurally and functionally distinct. Furthermore, a search of more than one (1) of the fusion protein sequences claimed in claim 25 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) nucleic acid sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) nucleic acid sequence from claim 25 for prosecution with Group VIII.

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Should Applicants elect to prosecute Group IX or X, each of these Groups is subject to further restriction as follows.

Claim 40 claims fusion protein SEQ ID Nos. 6, 8, 12, 14, 18, and 20. The instant fusion protein sequences are considered to be unrelated, since each sequence claimed is structurally and functionally distinct. Furthermore, a search of more than one (1) of the fusion protein sequences claimed in claim 40 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) fusion protein sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) fusion protein sequence from claim 40 for prosecution with Group IX or X.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on Mon–Fri, 8:00 am–4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval system (PAIR). Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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